DATE: January 14, 2016

TO: Steph Tathum

Office of Information and Regulatory Affairs (OIRA)

Office of Management and Budget (OMB)

FROM: Hilary Forster

Office of Planning, Research and Evaluation (OPRE)

Administration for Children and Families (ACF)

SUBJECT: Request for Non-Substantive Change to Health Profession Opportunity Grants (HPOG) Second Generation National and Tribal Evaluation (OMB Control Number 0970-0462)

This memo requests approval for revisions to consent forms for an evaluation of the Health Profession Opportunity Grants (HPOG). The consent forms were previously approved under OMB Control Number 0970-0462. The revisions have been made as a result of comments by Abt’s Institutional Review Board on the versions OMB reviewed. The remainder of this memo provides background on the HPOG evaluation and the nature of revisions made to the consent forms.

**Background on Research on HPOG**

ACF has funded a series of programs and related evaluations to examine “career pathways” approaches to providing post-secondary education and training; i.e., training that is organized as a series of manageable steps leading to successively higher credentials and employment opportunities in growing occupations. These programs and related evaluations include two rounds of program funding and associated evaluations for the **Health Profession Opportunity Grants (HPOG) Program. HPOG** grants provide funding to government agencies, community‑based organizations, post-secondary educational institutions, and tribal-affiliated organizations to provide education and training services to Temporary Assistance for Needy Families (TANF) recipients and other low-income individuals, including tribal members. In addition, ACF is funding the **Pathways for Advancing Careers and Education (PACE)** project, a rigorous evaluation of next-generation strategies for increasing the economic self-sufficiency of low-income individuals and families. Three HPOG grantees are also participating in PACE.

Funding for a first round of HPOG was awarded in 2010. Evaluation of the first round of HPOG grants has been underway since 2011 under OMB Control Number 0970-0397. The evaluation includes implementation, outcome and impact studies of the non-tribal HPOG grants, and implementation and outcome studies of the tribal grants. ACF awarded a second round of grants – referred to as HPOG Second Generation, or HPOG 2.0 – in 2015. An evaluation of these programs is getting underway, with a similar scope for evaluations of the tribal and non-tribal HPOG grantees.

Like the first-round evaluation, the HPOG 2.0 non-tribal evaluation will focus on estimating the impacts of the HPOG 2.0 Program to inform future program design and improvement. Key participant outcomes to be measured and analyzed will include completion of education and training, receipt of certificates and/or degrees, earnings, and employment in a healthcare career. The evaluation will also include an implementation study and cost benefit analysis.

Under the non-tribal evaluation (also known as the National Evaluation, to distinguish it from the evaluation of tribal grantees), applicants who qualify for the HPOG 2.0 program will be randomly assigned to a treatment group that can receive HPOG 2.0 program services or a control group that cannot. Programs will be expected to conduct random assignment of applicants to the HPOG 2.0 program, with some exceptions. Participants in the impact study of the first round of HPOG grants who apply for HPOG 2.0 will generally be excluded from random assignment (as discussed in more detail below). In addition, tribal programs will not implement random assignment.

OMB previously approved baseline data collection and two versions of an informed consent form for the HPOG 2.0 evaluation under OMB Control Number 0970-0462 – one consent form for applicants who will be randomly assigned and a second version for applicants who will not be randomly assigned.

**Reason for the Non-Substantive Change Request**

When OMB reviewed and approved the original HPOG Second Generation National and Tribal Evaluation information collection request , the evaluation contractor’s IRB (Abt Associates IRB) had not yet reviewed and approved the consent forms. Following review, the Abt Associates IRB requested some changes. These changes do not increase the burden on potential study participants required to complete the form. Instead, the changes merely simplify the language to make the forms easier to understand. In addition, revisions were made to clarify key items such as (but not limited to):

* Who the researchers are: the original submission did not list the organization names of the evaluation team members, which is required in a consent form;
* How the researchers will use the data: the IRB required more specific information about from what agencies the research team will collect administrative data and over what period; and
* For how long the researchers will use the data.

In addition, since OMB approval, OPRE, in consultation with the Abt IRB, agreed that prior HPOG and PACE participants who were randomly assigned in the first impact studies would not be subject to random assignment again. Specifically, OPRE and Abt used two main rules to guide decisions regarding the random assignment status of study participants from the earlier evaluation:

1. An individual should not have to go through random assignment twice; and
2. An individual’s current program of study should not be interrupted for the sake of random assignment.

The guidance applies both to individuals who are included in the experimental study of the first round of HPOG or the PACE study, as well as other prior participants in the first round of HPOG or PACE who are not in the experimental studies. Thus, some participants in the HPOG 2.0 national evaluation will bypass random assignment. These individuals will complete the non-random assignment consent form.

This request seeks approval of revised versions of both informed consent forms:

1. The “random assignment required” consent form, for use by study participants who are subject to random assignment in the National Evaluation; and
2. The “no-random assignment required” form, for use by individuals in the National Evaluation that are exempt from random assignment, and for applicants at tribal grantees participating in the federal Tribal Evaluation.

*Revised Materials*

We include revised consent forms with this memo. In addition, for each form, we attach a side-by-side comparison of the language approved by OMB and the current language as approved by the Abt IRB.

In addition, we revised Supporting Statement B to reflect changes in random assignment procedures. We revised Supporting Statement A to reflect a decrease in burden estimates; since OMB approval, 32 HPOG 2.0 grants were awarded rather than the 40 grants anticipated. The smaller number of grants awarded decreased the overall estimated number of HPOG participants.

**Expected Benefits**

We expect the requested changes to improve the overall flow, content, accuracy, and comprehension level of the forms. This will make it easier for potential participants to understand what the study requirements are, how their data will be used, and how they can participate.

**Attachment 1: Section by Section Comparison of Informed Consent Form A (Random Assignment Required)**

| **Section of Consent Form** | **Text as previously approved by OMB** | **As revised per Abt Associates IRB guidance** |
| --- | --- | --- |
| Introduction | The Health Profession Opportunity Grants (HPOG) Program is a job training program funded by the Administration for Children and Families (ACF) in the U.S. Department of Health and Human Services (HHS) in Washington, DC. The HPOG program is intended to help people improve their skills, find jobs, and advance in healthcare careers. Our local program, [name of HPOG program], receives funding from this national HPOG program. HHS is also funding research to study how well our program works in helping people get training and jobs, including the *Next Generation of HPOG Programs Impact Study* (Next Gen HPOG Impact Study). Over the next several years, researchers will be using information about people in the program to do their studies. This form: 1) describes the research study and 2) requests your participation in the study. We need to tell you about the study and what it means to be part of it. Only individuals who agree to participate in the study will be able to enroll in our [name of HPOG program] HPOG program.***Research Overview****The Next Generation of HPOG Programs Impact Study (Next Gen HPOG Impact Study*). For up to five years, [name of local HPOG program] will be in the Next Gen HPOG Impact Study. The study will assess if and how HPOG makes a difference in people’s lives by helping them complete training and get healthcare jobs. The study also will help the government learn how to improve the HPOG program, and similar programs, in the future.  | You are invited to take part in an important study of healthcare training programs. The study is funded by the U.S. Department of Health and Human Services. Several research organizations – including but not limited to, Abt Associates and its partners, MEF, the Urban Institute, Insight Policy Research, Abt SRBI and other researchers – are running the study for the U.S. Department of Health and Human Services. Your taking part in the study will help us learn more about how the HPOG program helps people improve their skills, find jobs, and advance in healthcare careers.Over the next 10 years, researchers will use information about people in the program to do the study. This form: 1) describes the HPOG Impact study and 2) requests your participation in the study. We need to tell you about the study and what it means to be part of it. Only individuals who agree to participate in the study will be able to enroll in our [name of HPOG program]. |
| Study requirements | *What does it mean to be part of the study?* As part of the impact study: 1. The study team will collect data from all eligible applicants of the [name of HPOG program] program when they are first applying to the program.
2. During the period of the impact study, entry into the HPOG program will be by lottery. If you are an eligible applicant for [name of HPOG program], you will take part in a lottery to see if you will be invited to participate in [name of HPOG program]. Some applicants may be invited to enroll in an “enhanced HPOG program (slightly different from the regular HPOG program in that it offers additional “enhanced” services), as well. If you are not invited to participate, you will not be able to enroll in [name of HPOG program]. However, you can enroll in any other service or program for which you are eligible.
3. The study team will collect follow-up information from people who enrolled in the [name of HPOG program] program, people enrolled in the “enhanced” HPOG program (if applicable), and people who were not invited to enroll in the program. This follow-up will include collecting updated contact information about every four months and then more detailed follow-up surveys will likely happen fifteen months and three years after people have applied to [name of HPOG program]).

We expect up to 52,500 people at 35 HPOG grantees to participate in the Next Gen HPOG Impact Study. Participation in this study is voluntary. If you choose not to be a part of this study, you will not be able to participate in the lottery for the HPOG program. You can, however, enroll in any other service or program for which you are eligible. | ***What does it mean to be part of the impact study?*** We expect a total of 43,000 people at up to 27 HPOG programs across the country to participate in this study. Entry into the HPOG program will be by computer lottery. Participation in the study is voluntary. You can choose not to be part of the study but that also means that you will not be part of the lottery and have a chance to be in the HPOG program. If you choose not to be part of the study you can, however, enroll in any other non-HPOG program or services in the community for which you are eligible. 1. If you agree to take part, staff at [NAME OF HPOG PROGRAM] will first see if you are eligible for the program. If you are eligible, then staff will explain that you must be in the lottery. The lottery will decide at random, whether or not you can take part in the [NAME OF HPOG PROGRAM]. If you are not selected, you will not be able to enroll in [NAME OF HPOG PROGRAM]. However, you can still enroll in any other service or program for which you are eligible.
2. The study team will collect data from all people who apply for HPOG and meet [NAME OF HPOG PROGRAM] eligibility requirements. This will happen when people first apply to the program and meet its eligibility rules.
3. The study team also plans to follow up with some of the people who participate in the study. The study team will keep track of people who participated in the lottery and were invited to enroll in the program. The study team also plans to follow-up with those who were not invited to enroll in the program. The study team will contact this group every three months to make sure that it has people’s current phone numbers and addresses. They will also have phone or in person interviews with this group approximately one and three years after they agreed to be in the study.
 |
| Information Collection | *What type of information will the study collect?* The researchers need your permission to get information about you so they can understand the types of people in the program and how well the program is working. For the impact study, researchers want: 1. Information you provide [name of HPOG program] when you first apply to the program including:
	1. Current information about you, your family, your education, and your work history; and
	2. If you have children, researchers would like to request information about their birthdates and names. Researchers may also contact you in the future about including your children in a related study. You can participate in this study even if you do not want your children to participate in another future study.
2. If you are invited to participate in [name of HPOG program] or the enhanced HPOG program, information you or other organizations provide to program staff about the training and services you get while you are in the program.
3. Information from follow-up surveys, including:
	1. Updated information about you, your family, your education, and your work history;
	2. Information about the training and services you get in the program or information about training and services you get outside the program if you are not in the HPOG program;
	3. If you have children, updated information on your children including their experiences at home and school. You can participate in this study even if you choose later not to answer questions about your children in another future study; and
	4. Updated contact information every four months or so to make sure the study team knows the best way to reach you.
4. Personal data such as your Social Security number so they can get information from government sources about your future employment, earnings, and education.

You may refuse to answer any specific question about yourself or your children at any time, but we encourage you to answer the questions. By participating in this study, you will help the federal government and programs around the country learn about the best way to provide training and help people get a healthcare job.  | ***What type of information will the study collect?***If you agree to participate in the lottery, researchers would like to collect the following information about you: 1. Information you provide when you first apply to the program including:
	1. Current information about you, your family, your education, your income and your work history. This includes social security numbers.
	2. If you have children, researchers would like to request information about their birthdates and names. Researchers may contact you in the future about including your children in a related study. You can participate in this study even if you do not want your children to participate in a study in the future.
2. Information you or other organizations provide to the [NAME OF HPOG PROGRAM] staff about the training and services you get while you are in the program.
3. Information from follow-up surveys. Some of the people in the study will be asked to answer a 60-minute phone or in-person survey. You can choose whether you want to participate in the survey or not. If you decide to participate in the survey you can choose not to answer any question. Whether or not you choose to participate in the survey will never affect any benefits or services you receive now or in the future. If you are selected you will be asked for:
	1. Updated information about you, your family, your education, your income .and your work history;
	2. Information about the training and education or employment support services you have received;
	3. If you have children, updated information on your children including their educational experiences such as grades, socialization skills, goals and support system; their activities outside of school, family routines and other outcomes.;
	4. Updated contact information every three months or so to make sure the study team knows the best way to reach you. The research study team (Abt Associates and Abt SRBI) may contact you via email, text or social media if you indicate it is okay to do so in your intake interview.
4. Information from government sources so researchers can learn more about your future employment, earnings, and post-secondary education over the next few years. Abt will use your name and social security number to get some of these data from the National Directory of New Hires and the National Student Clearinghouse. We will collect these data for you and up to 43,000 others study participants. The researchers will collect data for the 12 month period before you enrolled and up to five years after you enroll in the study.
 |
| Privacy  | *Will my information be kept private?* Researchers will use data security procedures to keep all of the study data private and to protect your personal information. All of the information used in research will be kept private to the extent allowed by law. However, there is a small risk of a breach of privacy. Strong precautions will be taken to make sure this does not happen. Your name will never appear in any report or with any research findings. The researchers will combine the information about everyone in the program to analyze how the program helps people improve their skills, find jobs, and advance in healthcare careers. Any forms or other papers that include your name will be kept in a locked storage area. Any computer files with your name will be locked and protected. Any researchers using information to study the program must follow all data security procedures and sign a privacy agreement.  | ***Will my information be kept private?*** The research organizations conducting this study will have access to the data being collected about you. These organizations are committed to keeping your personal information private. Any researchers using information to study the program must follow strict data security procedures and sign a privacy agreement. However, there is a small risk of a loss of privacy. We will take strong precautions to make sure this does not happen. Any piece of paper that includes your name or other identifying information will be kept in a locked storage area and will be destroyed after the study ends. Any computer files with your name or other identifying information will be protected by a password and will be stored on a secure network. Your personal information will be protected to the extent allowable by law. Our reports will combine your responses with responses from others. People who read the reports will not be able to identify responses you give. Any data sets that are developed for sharing with other researchers will be stripped of information that would make it easy to identify you. |
| Requesting Permission | ***Requesting Your Permission***This agreement is effective from the date you sign it (shown below) until the end of HHS’s research on the next generation of HPOG grants, or when you choose to withdraw permission. You may choose to withdraw your participation at any time. If you do withdraw, researchers will continue to use information collected during the time you consented. To withdraw from the study, please contact someone at the [name of HPOG program]. You will receive a copy of this form for your records. An agency may not conduct and a person is not required to respond to an information collection request unless it displays a currently valid OMB control number.For questions or concerns about your rights as a research participant, call Teresa Doksum at the Abt Associates Institutional Review Board at toll-free 877-520-6835. For questions or concerns about the research, call [XXX] at XXX-XXX-XXXX.  | ***Requesting Permission***This agreement is effective from the date you sign it (shown below) until the end of HHS’s research on HPOG grants, or when you choose to withdraw permission. You may choose to withdraw your participation in the study at any time. If you do withdraw, researchers will continue to use information collected during the time you consented. To withdraw from the study, please call toll-free at 844-717-4691 (the Abt help line).You will receive a copy of this form for your records. An agency may not collect information and a person is not required to respond to an information collection request unless it displays a currently valid OMB control number. For questions or concerns about the research, call Abt Associates toll-free at 844-717-4691. For questions or concerns about your rights as a research participant, call Teresa Doksum at the Abt Associates Institutional Review Board at toll-free 877-520-6835.  |
| Statement | “I have read this form and agree to allow information about me to be used in the Next Generation of HPOG Programs Impact Study and in other HPOG research studies. I know that my participation in the research study is voluntary, that researchers will use data security procedures to keep all of the study information private as described above, and that my name will never appear in any public report. I know that I can refuse to answer any questions researchers might ask me, and that I can stop being included in the research at any time without penalty. I understand that researchers will use my personal information to get information about me from other sources, as described above.” Print Name of Study Participant If you agree to let Researchers use your information, sign above date If You Do Not Agree to Let Researchers Use Your Information, Sign Above Date**Parent or Guardian *for HPOG applicants under the age of 18, your parent or legal guardian also* *must sign below:*** Print Name of Parent/Guardian If you agree to let researchers use your Child’s information, sign above date If You Do Not Agree to Let Researchers Use Your Child’s Information, Sign Above Date | ***Statement***“I have read this form and agree to participate in the Health Profession Opportunity Grant Program research study. * **I know that I must agree to be in the research study before I can enroll in the [NAME OF HPOG PROGRAM].**
* **I know if I agree to be in the research study, I will be selected by the lottery to be in the HPOG program. I understand that even if I am not selected to be in the program, I will still be in the research study.”**

PRINT YOUR NAME ABOVE DATEI AGREE to be in the research STUDY, SIGN ABOVE**Parent or Guardian *for HPOG applicants under the age of 18, your parent or legal guardian also* *must sign below:*** Print Name of Parent/Guardian If you agree to let researchers use your Child’s information, sign above date If You Do Not Agree to Let Researchers Use Your Child’s Information, Sign Above DateAccording to the Paperwork Reduction Act of 1995 *(Pub. L. 104-13)*, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is 0970 0462. The described information collection is voluntary. If you have comments or suggestions for improving this form, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance Officer. |

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|  | OMB Control No. 0970-0462OMB approval expires 8/31/2018Abt Associates IRB Approval No. TBDUrban Institute IRB Approval No. xxxx |

**Attachment 2:**

**AGREEMENT TO TAKE PART IN THE
HEALTH PROFESSION OPPORTUNITY GRANT PROGRAM (HPOG)**

**RESEARCH STUDY—**

**FORM A: ADULT LOTTERY REQUIRED**

**+ PARENT PERMISSION BOX FOR MINORS**

## You are invited to take part in an important study of healthcare training programs. The study is funded by the U.S. Department of Health and Human Services. Several research organizations – including but not limited to, Abt Associates and its partners, MEF, the Urban Institute, Insight Policy Research, Abt SRBI and other researchers – are running the study for the U.S. Department of Health and Human Services. Your taking part in the study will help us learn more about how the HPOG program helps people improve their skills, find jobs, and advance in healthcare careers.

Over the next 10 years, researchers will use information about people in the program to do the study. This form: 1) describes the HPOG Impact study and 2) requests your participation in the study. We need to tell you about the study and what it means to be part of it. Only individuals who agree to participate in the study will be able to enroll in our [name of HPOG program].

***What does it mean to be part of the impact study?***

We expect a total of 43,000 people at up to 27 HPOG programs across the country to participate in this study. Entry into the HPOG program will be by computer lottery. Participation in the study is voluntary. You can choose not to be part of the study but that also means that you will not be part of the lottery and have a chance to be in the HPOG program. If you choose not to be part of the study you can, however, enroll in any other non-HPOG program or services in the community for which you are eligible.

1. If you agree to take part, staff at [NAME OF HPOG PROGRAM] will first see if you are eligible for the program. If you are eligible, then staff will explain that you must be in the lottery. The lottery will decide at random, whether or not you can take part in the [NAME OF HPOG PROGRAM]. If you are not selected, you will not be able to enroll in [NAME OF HPOG PROGRAM]. However, you can still enroll in any other service or program for which you are eligible.
2. The study team will collect data from all people who apply for HPOG and meet [NAME OF HPOG PROGRAM] eligibility requirements. This will happen when people first apply to the program and meet its eligibility rules.
3. The study team also plans to follow up with some of the people who participate in the study. The study team will keep track of people who participated in the lottery and were invited to enroll in the program. The study team also plans to follow-up with those who were not invited to enroll in the program. The study team will contact this group every three months to make sure that it has people’s current phone numbers and addresses. They will also have phone or in person interviews with this group approximately one and three years after they agreed to be in the study.

***What type of information will the study collect?***

If you agree to participate in the lottery, researchers would like to collect the following information about you:

1. Information you provide when you first apply to the program including:
	1. Current information about you, your family, your education, your income and your work history. This includes social security numbers.
	2. If you have children, researchers would like to request information about their birthdates and names. Researchers may contact you in the future about including your children in a related study. You can participate in this study even if you do not want your children to participate in a study in the future.
2. Information you or other organizations provide to the [NAME OF HPOG PROGRAM] staff about the training and services you get while you are in the program.
3. Information from follow-up surveys. Some of the people in the study will be asked to answer a 60-minute phone or in-person survey. You can choose whether you want to participate in the survey or not. If you decide to participate in the survey you can choose not to answer any question. Whether or not you choose to participate in the survey will never affect any benefits or services you receive now or in the future. If you are selected you will be asked for:
	1. Updated information about you, your family, your education, your income .and your work history;
	2. Information about the training and education or employment support services you have received;
	3. If you have children, updated information on your children including their educational experiences such as grades, socialization skills, goals and support system; their activities outside of school, family routines and other outcomes.;
	4. Updated contact information every three months or so to make sure the study team knows the best way to reach you. The research study team (Abt Associates and Abt SRBI) may contact you via email, text or social media if you indicate it is okay to do so in your intake interview.
4. Information from government sources so researchers can learn more about your future employment, earnings, and post-secondary education over the next few years. Abt will use your name and social security number to get some of these data from the National Directory of New Hires and the National Student Clearinghouse. We will collect these data for you and up to 43,000 others study participants. The researchers will collect data for the 12 month period before you enrolled and up to five years after you enroll in the study.

***Will my information be kept private?***

The research organizations conducting this study will have access to the data being collected about you. These organizations are committed to keeping your personal information private. Any researchers using information to study the program must follow strict data security procedures and sign a privacy agreement. However, there is a small risk of a loss of privacy. We will take strong precautions to make sure this does not happen. Any piece of paper that includes your name or other identifying information will be kept in a locked storage area and will be destroyed after the study ends. Any computer files with your name or other identifying information will be protected by a password and will be stored on a secure network. Your personal information will be protected to the extent allowable by law. Our reports will combine your responses with responses from others. People who read the reports will not be able to identify responses you give. Any data sets that are developed for sharing with other researchers will be stripped of information that would make it easy to identify you.

***Requesting Permission***

This agreement is effective from the date you sign it (shown below) until the end of HHS’s research on HPOG grants, or when you choose to withdraw permission. You may choose to withdraw your participation in the study at any time. If you do withdraw, researchers will continue to use information collected during the time you consented. To withdraw from the study, please call toll-free at 844-717-4691 (the Abt help line).

You will receive a copy of this form for your records. An agency may not collect information and a person is not required to respond to an information collection request unless it displays a currently valid OMB control number.

For questions or concerns about the research, call Abt Associates toll-free at 844-717-4691. For questions or concerns about your rights as a research participant, call Teresa Doksum at the Abt Associates Institutional Review Board at toll-free 877-520-6835.

***Statement***

“I have read this form and agree to participate in the Health Profession Opportunity Grant Program research study.

* **I know that I must agree to be in the research study before I can enroll in the [NAME OF HPOG PROGRAM].**
* **I know if I agree to be in the research study, I will be selected by the lottery to be in the HPOG program. I understand that even if I am not selected to be in the program, I will still be in the research study.”**

PRINT YOUR NAME ABOVE DATE

I AGREE to be in the research STUDY, SIGN ABOVE

**Parent or Guardian *for HPOG applicants under the age of 18, your parent or legal guardian also must sign below:***

**By signing this participation agreement, I confirm that I have read and understood the description of the HPOG Research Study. I agree to the participation of my child in this study.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**NAME OF PARENT/GUARDIAN (Printed) SIGNATURE OF PARENT/GUARDIAN**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**DATE**

ADD IRB STAMP

According to the Paperwork Reduction Act of 1995 *(Pub. L. 104-13)*, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is 0970-0462. The described information collection is voluntary. If you have comments or suggestions for improving this form,, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance Officer.

**Attachment 3: Section by Section Comparison of Informed Consent Form B (Random Assignment NOT Required)**

|  |  |  |
| --- | --- | --- |
| **Section of Consent Form** | **Text as previously approved by OMB** | **As revised per Abt Associates IRB guidance** |
| Introduction and study requirements | The Health Profession Opportunity Grants (HPOG) Program is a job training program funded by the Administration for Children and Families (ACF) in the U.S. Department of Health and Human Services (HHS) in Washington, DC. The HPOG program is intended to help people improve their skills, find jobs, and advance in healthcare careers. Our local program, [name of HPOG program], receives funding from this national HPOG program. HHS is also funding research to study how well our program works in helping people get training and jobs. ***Research Overview***Over the next several years, researchers will be using information about people in the program to do their studies. By participating in the studies, you will help us, the federal government, and programs around the country learn about the best way to provide training and help participants get a healthcare job. You will be asked for information at certain times during your participation in the program and after you leave the program. You may be contacted by a researcher after you leave the program to answer some questions about your experiences. While we encourage you to answer their questions, you may refuse to answer them. | You are invited to take part in an important study of healthcare training programs. The study is funded by the U.S. Department of Health and Human Services. Several research organizations – including MEF, the Urban Institute, and Insight Policy Research and other researchers – are running the study for the U.S. Department of Health and Human Services. Your taking part in the study will help us learn more about how the HPOG program helps people improve their skills, find jobs, and advance in healthcare careers.Over the next 10 years, researchers will use information about people in the program to do the study. This form: 1) describes the HPOG Outcome study and 2) requests your participation in the study. We need to tell you about the study and what it means to be part of it. |
| ***What does it mean to be part of the Outcomes study?*** We expect a total of 43,000 people at up to 27 HPOG programs across the country to participate in this study. Participation in the HPOG Outcome study is voluntary. You can choose not to be part of the study and still receive HPOG services. The study team will collect data from all people who apply for HPOG and meet [NAME OF HPOG PROGRAM] eligibility requirements. This will happen when people first apply to the program and meet its eligibility rules.  |
| Information Collection | *What type of information will the studies collect?* The researchers need your permission to get information about you so they can understand the types of people in the program and how well the program is working. For the research studies, researchers want:1. Information you provide [name of HPOG program] when you first apply to the program including current information about you, your family, your education, and your work history;
2. If you have children, researchers would like to request information about their birthdates and names. Researchers may also contact you in the future about including your children in a related study. You can participate in research studies even if you do not want your children to participate in future studies.
3. Information you provide to [name of HPOG program] about the training and services you get while you are in the program; and
4. Personal data such as your Social Security number so they can get information from government sources about your future employment, earnings, and education.

Participating in research studies is voluntary. You may withdraw your permission to share data at any time. Refusing to provide permission for research now, or withdrawing permission for research later, will not affect your eligibility for any services in this program or elsewhere. If you withdraw, researchers may continue to use information that was collected about you during the period that you did give permission for research. | ***What type of information will the study collect?***If you agree to participate in the study, researchers would like to collect the following information about you: 1. Information you provide when you first apply to the program including: current information about you, your family, your education, your income and your work history. This includes social security numbers.
2. Information you or other organizations provide to the [NAME OF HPOG PROGRAM] staff about the training and services you get while you are in the program.
3. Information from government sources so researchers can learn more about your future employment, earnings, and post-secondary education over the next few years. Abt will use your name and social security number to get some of these data from the National Directory of New Hires and the National Student Clearinghouse.
 |
| Privacy  | *Will my information be kept private?* Researchers will use data security procedures to keep all of the study data private and to protect your personal information. All of the information used in research will be kept private to the extent allowed by law. However, there is a small risk of a breach of privacy. Strong precautions will be taken to make sure this does not happen. Your name will never appear in any report or with any research findings. The researchers will combine the information about everyone in the program to analyze how the program helps people improve their skills, find jobs, and advance in healthcare careers. Any forms or other papers that include your name will be kept in a locked storage area, and any computer files with your name will be locked and protected. Any researchers using information to study the program must follow all data security procedures and sign a privacy agreement. | ***Will my information be kept private?*** The research organizations conducting this study will have access to the data being collected about you. These organizations are committed to keeping your personal information private. Any researchers using information to study the program must follow strict data security procedures and sign a privacy agreement. However, there is a small risk of a loss of privacy. We will take strong precautions to make sure this does not happen. Any piece of paper that includes your name or other identifying information will be kept in a locked storage area and will be destroyed after the study ends. Any computer files with your name or other identifying information will be protected by a password and will be stored on a secure network. Your personal information will be protected to the extent allowable by law. Our reports will combine your responses with responses from others. People who read the reports will not be able to identify responses you give. Any data sets that are developed for sharing with other researchers will be stripped of information that would make it easy to identify you. |
| Requesting Permission | ***Requesting Your Permission***This agreement is effective from the date you sign it (shown below) until the end of HHS’s research on the next generation of HPOG grants, or when you choose to withdraw permission. You will receive a copy of this form for your records. An agency may not conduct and a person is not required to respond to an information collection request unless it displays a currently valid OMB control number.For questions or concerns about your rights as a research participant, call Teresa Doksum at the Abt Associates Institutional Review Board at toll-free 877-520-6835. For questions or concerns about the research, call [XXX] at XXX-XXX-XXXX (toll free). | ***Requesting Permission***This agreement is effective from the date you sign it (shown below) until the end of HHS’s research on HPOG grants, or when you choose to withdraw permission. You may choose to withdraw your participation in the study at any time. If you do withdraw, researchers will continue to use information collected during the time you consented. To withdraw from the study, please call toll-free at 844-717-4691 (the Abt help line).You will receive a copy of this form for your records. An agency may not conduct and a person is not required to respond to an information collection request unless it displays a currently valid OMB control number. For questions or concerns about the research, call Abt Associates toll-free at 844-717-4691.For questions or concerns about your rights as a research participant, call Teresa Doksum at the Abt Associates Institutional Review Board at toll-free 877-520-6835.  |
| Statement | ***Statement***“I have read this form and agree to allow information about me to be used in the Health Profession Opportunity Grants Program Next Generation research studies. I know that my participation in the research study is voluntary, that researchers will use data security procedures to keep all of the study information private as described above, and that my name will never appear in any public report. I know that I can refuse to answer any questions researchers might ask me, and that I can stop being included in the research at any time without penalty. I understand that researchers will use my personal information to get information about me from other sources, as described above.” Print Name of Study Participant If you agree to let Researchers use your information, sign above date If You Do Not Agree to Let Researchers Use Your Information, Sign Above Date**Parent or Guardian *for HPOG applicants under the age of 18, your parent or legal guardian also* *must sign below:*** Print Name of Parent/Guardian If you agree to let researchers use your Child’s information, sign above date If You Do Not Agree to Let Researchers Use Your Child’s Information, Sign Above Date | ***Statement***“I have read this form and **I know that my participation in the study is voluntary and I still may receive HPOG services if I choose not to participate.** * I agree to be in the research study
* I do not agree to be in the research study

 Print Name of Study Participant DATEAccording to the Paperwork Reduction Act of 1995 *(Pub. L. 104-13)*, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is 0970-0462. The described information collection is voluntary. If you have comments or suggestions for improving this form,, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance Officer. |

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| --- | --- |
|  | OMB Control No. 0970-0462OMB approval expires 8/31/2018Abt Associates IRB Approval No. TBDUrban Institute IRB Approval No. xxxx |

**Attachment 4: AGREEMENT TO TAKE PART IN THE
HEALTH PROFESSION OPPORTUNITY GRANT PROGRAM (HPOG)**

**OUTCOME STUDY—**

**FORM B: ADULT LOTTERY NOT REQUIRED**

**+ PARENT PERMISSION BOX FOR MINORS**

## You are invited to take part in an important study of healthcare training programs. The study is funded by the U.S. Department of Health and Human Services. Several research organizations – including MEF, the Urban Institute, and Insight Policy Research and other researchers – are running the study for the U.S. Department of Health and Human Services. Your taking part in the study will help us learn more about how the HPOG program helps people improve their skills, find jobs, and advance in healthcare careers.

Over the next 10 years, researchers will use information about people in the program to do the study. This form: 1) describes the HPOG Outcome study and 2) requests your participation in the study. We need to tell you about the study and what it means to be part of it.

***What does it mean to be part of the Outcomes study?***

We expect a total of 43,000 people at up to 27 HPOG programs across the country to participate in this study. Participation in the HPOG Outcome study is voluntary. You can choose not to be part of the study and still receive HPOG services.

The study team will collect data from all people who apply for HPOG and meet [NAME OF HPOG PROGRAM] eligibility requirements. This will happen when people first apply to the program and meet its eligibility rules.

***What type of information will the study collect?***

If you agree to participate in the study, researchers would like to collect the following information about you:

1. Information you provide when you first apply to the program including: current information about you, your family, your education, your income and your work history. This includes social security numbers.
2. Information you or other organizations provide to the [NAME OF HPOG PROGRAM] staff about the training and services you get while you are in the program.
3. Information from government sources so researchers can learn more about your future employment, earnings, and post-secondary education over the next few years. Abt will use your name and social security number to get some of these data from the National Directory of New Hires and the National Student Clearinghouse.

***Will my information be kept private?***

The research organizations conducting this study will have access to the data being collected about you. These organizations are committed to keeping your personal information private. Any researchers using information to study the program must follow strict data security procedures and sign a privacy agreement. However, there is a small risk of a loss of privacy. We will take strong precautions to make sure this does not happen. Any piece of paper that includes your name or other identifying information will be kept in a locked storage area and will be destroyed after the study ends. Any computer files with your name or other identifying information will be protected by a password and will be stored on a secure network. Your personal information will be protected to the extent allowable by law. Our reports will combine your responses with responses from others. People who read the reports will not be able to identify responses you give. Any data sets that are developed for sharing with other researchers will be stripped of information that would make it easy to identify you.

***Requesting Permission***

This agreement is effective from the date you sign it (shown below) until the end of HHS’s research on HPOG grants, or when you choose to withdraw permission. You may choose to withdraw your participation in the study at any time. If you do withdraw, researchers will continue to use information collected during the time you consented. To withdraw from the study, please call toll-free at 844-717-4691 (the Abt help line).

You will receive a copy of this form for your records. An agency may not conduct and a person is not required to respond to an information collection request unless it displays a currently valid OMB control number.

For questions or concerns about the research, call Abt Associates toll-free at 844-717-4691

For questions or concerns about your rights as a research participant, call Teresa Doksum at the Abt Associates Institutional Review Board at toll-free 877-520-6835.

***Statement***

“I have read this form and **I know that my participation in the study is voluntary and I still may receive HPOG services if I choose not to participate.**

* I agree to be in the research study
* I do not agree to be in the research study

PRINT YOUR NAME ABOVE

DATE

**Parent or Guardian *for HPOG applicants under the age of 18, your parent or legal guardian also* *must sign below:***

Print Name of Parent/Guardian

If you agree to let researchers use your Child’s information, sign above date

If You Do Not Agree to Let Researchers Use Your Child’s Information, Sign Above Date

ADD IRB STAMP

According to the Paperwork Reduction Act of 1995 *(Pub. L. 104-13)*, no persons are required to respond to a collection of information unless such collection displays a valid OMB control number. The valid OMB control number for this information collection is 0970 0462. The described information collection is voluntary. If you have comments or suggestions for improving this form,, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance Officer.